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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,770	02/27/2004	Robert S. Biscup	SPIN 2 13195-1	8517
<div>7590 05/22/2007 BRIAN E. TURUNG FAY, SHARPE, FAGAN, MINNICH &amp; McKEE Seventh Floor 1100 Superior Avenue Cleveland, OH 44114-2579</div>			<div>EXAMINER BAHTA, KIDEST</div>	
			<div>ART UNIT 2125</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 05/22/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/788,770		BISCUP, ROBERT S.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Kidest Bahta		2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 43-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-62 and 64-66 is/are rejected.
- 7) ☐ Claim(s) 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/27/04</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-47, 53-60 and 64-66 rejected under 35 U.S.C. 102(b) as being anticipated by Crook (US Patent 5,365,996).

Regarding claims 43, Crook discloses that a method for producing a custom prosthetic implant for insertion into a obtaining information about the site of implant for the prosthetic implant (Abstract); manually and/or electronically entering said obtained information about said site for processing by at least one data processor (column 3, lines 32-41); processing said manually and/or electronically entered information by said at least one data processor to generate data for a multi-dimensional prosthetic implant (column 3, lines 54-66); at least partially transferring said generated data for a multi-dimensional prosthetic implant to a forming machine that is used to at least partially form said prosthetic implant (column 4, lines 7-15); at least partially forming said prosthetic implant by said forming machine (column 4, lines 41-55).

Regarding claims 44 and 45, Crook discloses the step of obtaining information is at least partially obtained mechanically, chemically, electronically, and combinations thereof and the step of at least partially obtaining information electronically includes obtaining information by an ultrasonic device, a sound wave device, a magnetic wave

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device, an electromagnetic wave device, a heat detecting device, a camera, a scope, and combinations thereof (column 4, lines 56-64; column 5, lines 16-20).

Regarding claim 46, Crook discloses the prosthetic device is at least partially formed of a biocompatible material (column 4, lines 7-15).

Regarding claim 47, Crook discloses the step of at least partially forming said prosthetic implant includes forming a material in said forming machine having a shape that is substantially similar to at least a portion of the multi-dimensional prosthetic implant generated by said at least one data processor (column 4, lines 41-55).

Regarding claim 53, Crook discloses prosthetic device includes at least one cavity, at least one outer wall opening, and combinations thereof (Fig. 6).

Regarding claim 54, Crook disclose the step of comparing said generated data for a multi-dimensional prosthetic implant to said obtained information about the site of implant, and further including the step of modifying said generated data when required (Fig. 11).

Regarding claim 55, Crook discloses forming machine including at least one mold cavity that can be varied in size, shape and combinations thereof (column 4, lines 7-15).

Regarding claim 56, Crook discloses the mold cavity is varied based at least partially on said generated data (column 4, lines 7-15).

Regarding claim 57, Crook discloses the said at least one data processor generates data that can be used to create at least one graphical representation of said prosthetic implant (Figs. 6-7).

Regarding claim 58, Crook discloses the including the step of manually modifying said generated data (Fig. 11).

Regarding claim 59, Crook discloses the said step of transferring at least a portion of the generated information to a molding machine includes a transmission device selected from the group consisting of wires, cables, electromagnetic waves, and combinations thereof (Fig. 3).

Regarding claim 60, Crook discloses the steps of flowing said at least one type of moldable compound into said forming machine, at least partially forming said prosthetic implant in said forming machine, and hardening at least a portion of said moldable compound (column 4, lines 16-55).

Regarding claim 66, Crook discloses the step of modifying at least a portion of said prosthetic implant after said prosthetic implant has been removed from said forming machine, said step of modifying including labeling, cutting, smoothing, minor sizing, disinfecting, etching, and combinations thereof (column 4, lines 16-55).

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-52, 61-62, 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crook (US Patent 5,365,996) in view of Dooley et al. (AUTOMATED

DESIGN AND ANALYSIS SYSTEM FOR DESIGN OF CUSTOM ORTHOPEDIC IMPLANTS).

Crook discloses that the limitations of claim 43 as stated in par. 1 but fails to disclose the limitations of claims 48-52, 61-62, 64-65. However, Dooley discloses that the limitations of 48-52, 61-62 and 64-65 as follows:

Regarding claims 48-52, Dooley discloses prosthetic device is formed at least partially bioabsorbable, partially moldable, one location marker, one biological additive, one biological additive (Fig.1).

Regarding claims 61-62, Dooley discloses the moldable compound is at least partially hardened by exposure to heat, radiation, catalysts, chemical reactants, electromagnetic waves, sound waves, and combinations thereof and the moldable compound includes a material selected from the group consisting of bone, cartilage, calcium-phosphate compounds, ceramics, metals, polymers, co-polymers, resins, thermoplastics, and mixtures thereof ((Page 406, i.e., implant constriction)

Regarding claims 64-65, Dooley discloses readable information on said prosthetic implant, said readable information including at least a portion of said history information said prosthetic implant is at least partially formed on or about at least one preexisting structure (Page 408, i.e., schemata).

It would have been obvious to a person of ordinary skill in the art at the time of invention was made to modify the teachings of Crook with the teaching of Dooley in order to provide an improved method of making an implantable joint prosthesis which can provide improved prosthesis shafts not only from the point of view of the geometry

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of the bone passage, but also can ensure an extremely uniform distribution of the stresses.

### ***Allowable Subject Matter***

3. Claim 63 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43-62 and 44-66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No.

6,786,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the organization elements in the claims and the functionality are merely obvious variations of each other. The instant application claims are border which read in the Patent 6,786,930.


### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed Kidest Bahta whose telephone number is 571-272-3737. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on 571-272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval IPAIRI system. Status information for published applications may be obtained from either Private PMR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAG system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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